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#11

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/029,042	05/15/98	KIM S	003364.P001

HM12/0615
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EXAMINER	
FITZGERALD,D	
ART UNIT	**PAPER NUMBER**
1646	5

DATE MAILED: 06/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/029,042	KIM, et al.
Examiner	**Group Art Unit**
David L. FITZGERALD	1646

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *ONE (1)* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-21* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice ... re Sequences

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 for the reason(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

Applicant is requested to return a copy of the attached Notice to Comply with the response to this action.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121 and 37 C.F.R. § 1.499:

I. An expression system for the production of erythropoietin (EPO), EPO nucleic acids employed therein, methods of making EPO proteins, and the proteins made in the expression system, upon which all of claims 1-21 are readable.

II. An expression system for the production of Factor VIII and methods of making Factor VIII proteins, upon which claims 18-21 are readable.

III. An expression system for the production of TPA and methods of making TPA proteins, upon which claims 18-21 are readable.

Because this application was filed under 35 U.S.C. § 371, the PCT Unity of Invention standard is applicable to the instant claims. 37 C.F.R. § 1.499.

Subsection (d) of 37 C.F.R. § 1.475, "Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage," provides:

> If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 37 C.F.R. § 1.476(c).

Accordingly, the main invention in the instant application comprises an expression system for the production of EPO, the corresponding recombinant reagents, methods of using them to make EPO, and the EPO made thereby. As evidenced by WO 89/03877 (cited and discussed in the International Preliminary Examination Report, PCT/IPEA/409), the expression of human proteins in avian expression systems, which is the only feature shared by all of groups I-III, is not *per se* novel and thus does not constitute a special technical feature which defines an advance over the

prior art within the meaning of PCT Rule 13.2. Inventions I-III are consequently not so linked as to form a single inventive concept as required by PCT Rule 13.1. Pursuant to 37 C.F.R. § 1.475(d), the DO/US considers that the systems for the production of the subsequently recited products, *viz.*, TPA and Factor VIII, do not correspond to the main invention. Restriction for examination purposes as indicated is accordingly proper.

3. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone	(703) 308-3934
Fax	
All formal papers	(703) 308-4242
Informal communications	(703) 308-0294
e-mail (note PTO policies below)	david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1 receptionists at (703) 308-0196.

DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

14 June 1999

The best **time to reach Examiner Fitzgerald** is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the acting supervisor for this Art Unit, Paula Hutzell, may be reached at (703) 308-4310.

Most official papers and all informal **communications may be submitted to the PTO by fax.** For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- Call the examiner when you send an urgent communication.
- **Do not send a duplicate copy** by mail or courier.

Any Internet **e-mail communications will be made of record in the application file**. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.

Application Serial No. 09/029,042

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. §§ 1.821-1.825 for the following reason(s):

[X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990, and at 55 FR 18230, May 1, 1990.

[ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. § 1.821(c).

[ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. § 1.821(e).

[ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. §§ 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing".

[ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 C.F.R. § 1.825(d).

[ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. § 1.821(e).

[ ] 7. Other:

Applicant must provide:

[X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

[X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

[X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821(e) or § 1.821(f) or § 1.821(g) or § 1.825(b) or § 1.825(d).

For questions regarding compliance with these requirements, please contact one of the following:

For rules interpretation, call (703) 308-4216.
For CRF submission help, call (703) 308-4212.
For PatentIn software help, call (703) 557-0400.

Please return a copy of this notice with your response.